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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,090	12/30/2005	Glynne Ivo Gut	065691-0428	8146

22428 7590 04/24/2007
FOLEY AND LARDNER LLP
SUITE 500
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WASHINGTON, DC 20007

EXAMINER	
STAPLES, MARK	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,090	GUT ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/31/2007*.

2a)☒ This action is **FINAL**., 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/30/2005 & 01/31/2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

1. Applicants' amendment of claims 1-6, 8, 12, 13, and 15 in the paper filed on 01/31/2007 is acknowledged.

Claims 1-17 are pending and at issue.

Applicant's arguments filed on 01/31/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn

2. The objection to the Title is withdrawn in light of the Applicant's amendment of the title.

3. The objection to the Abstract is withdrawn in light of the Applicant's amendment of the Abstract.

4. The objection for lack of a Brief Description of the Drawings is withdrawn in light of the Applicant's amendment to the specification to include a Brief Description of the Drawings.

5. The objection to claim 1 is withdrawn in light of the Applicant's correction of the misspelled word.

6. The objections to claim 8 are withdrawn in light of the Applicant's amendment of this claim.

7. The objection to claim 15 is withdrawn in light of the Applicant's correction of the misspelled word.

Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph

8. The rejections of claims 1-17 under 35 USC § 112 Second Paragraph are withdrawn in light of the Applicant's removal of the word "engineered" from claim 1.

9. The rejections of claims 2, 5, 6, and 7 under 35 USC § 112 Second Paragraph are withdrawn in light of the Applicant's removal of the words "not natural" from claim 2.

10. The rejections of claim 6 under 35 USC § 112 Second Paragraph is withdrawn in light of the Applicant's amendment of this claim to clarify the chemical formula.

11. The rejections of claims 5 and 6 under 35 USC § 112 Second Paragraph is withdrawn in light of the Applicant's amendment of these claims to define the incubation temperature.

Claim Rejections Withdrawn - 35 USC § 112 First Paragraph

12. The rejection of claim 12 under 35 USC § 112 First Paragraph is withdrawn in light of the Applicant's claim amendment to recite selection from the group consisting of MALDI and ESI.

Claim Rejections Withdrawn - 35 USC § 102

13. The rejections of claims 5 and 6 under 35 USC § 102 are withdrawn in light of Applicant's amendment of these claims. However new rejections are made under 35 USC § 103, see below.

Rejections that are Maintained

Sequence Compliance

14. The reply filed on 01/31/2007 is not fully responsive to the Office communication mailed on 11/04/2006 for the reason(s) set forth below or on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report.

Applicant is reminded that each sequence of ten or more nucleotides must be identified by a unique SEQ ID NO. The sequences in Figure 3 must be so identified. The sequences in the figures must be identified in the drawings or the Brief Description of the Drawings. The sequences given in Figure 4 for SEQ ID NO: 9, do not match the sequence listing file, appropriate correction is required. Due to non-compliance of sequence rules, the drawings filed on 01/31/2007 and 12/30/2005 are objected to.

Claim Rejections Maintained - 35 USC § 102

15. The rejection of claims 1-4 and 7-17 under 35 U.S.C. 102(b) as being anticipated by Stanton Jr. et al. (2003) are maintained.

Applicant's arguments filed on 01/31/2007 have been fully considered but they are not persuasive. Applicant has amended base claim 1 to recite detection of "known and unknown" DNA mutations. Applicant then argues that Stanton et al. (US Patent No.

6,565,059 published in 2003) does not disclose detection of unknown mutations, citing claims 1, 22, 56, and 65. However, Stanton, Jr. et al. do clearly disclose the detection of unknown variances:

> "As can be seen from the mass differences obtained (FIG. 6 and Table 5), the hypothesis was correct, the RFC mut primer was indeed missing one G. The power of the method of this invention [US Patent No. 6,565,059] is dramatically revealed in the above experiment. What began as a controlled test of the method using a known sequence and a known nucleotide variance actually detected an **unknown** variance in an unexpected place--the RFC mut primer" (**emphasis** by Examiner, see column 157m lines 40-44)

It is noted that Stanton Jr. et al. understand that the detection of the deletion of one G reveals that the method has the power to detect an unknown variance, that is to detect as well mutations, single polymorphisms, and insertions.

Applicant presents no arguments against the rejections of claims 2-17, other than these claims being dependent on claim 1. However, due to amendment of claims 5 and claim 6, the former rejections of these claims are withdrawn under 35 USC § 102 and new rejections are made below under 35 USC § 103.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton Jr. et al. (2003) as applied to claim 1 and 2 above, and further in view of Gish et al. (1988).

Regarding claims 5 and 6, Stanton Jr. et al. teach cleavage with heat if necessary (see column 143 lines 57-62), that is to perform cleavage at room temperature but apply heat if necessary, but do not specifically teach cleavage at 55°C.

Regarding claim 6, Stanton Jr. et al. do not specifically teach cleavage using compound having the formula OH-(CH2)n-I, where n = 2-5.

Regarding claim 6, Gish et al. specifically teach cleavage using iodoethanol which is the compound where n=2 for the formula OH-(CH2)n-I (see p. 1520, 3rd column, 1st sentence), and teach a cleavage temperatures of 56°C (see p. 1520, middle column, 1st sentence) and 95°C (see legend to Figure 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cleavage of Stanton Jr. et al. by using iodoethanol as suggested by Gish et al. at a temperature of 55°C with a

reasonable expectation of success. The motivation to do so is provided by Gish et al. who teach that iodoethanol can successfully be used as a cleaving agent and both Stanton Jr. et al. and Gish et al. who together teach that cleavage temperatures can be changed and can be in the range of room temperature to 95°C. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

17. No claim is free of the prior art.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-

9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
April 23, 2007

MS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/23/07

Notice to Comply	Application No. 10/563,090	Applicant(s) GUT ET AL.	
	Examiner Mark Staples	Art Unit 1637	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☒ 7. Other: See Office Action.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
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